disagrees. The petition and opposition reveal the parties' drastically different understandings of the law and the significance of the facts concerning the FDA approval of the 4004M pacemaker lead. For instance, Petitioners maintain that design specifications originate with the manufacturer and therefore are not specific federal requirements with preemptive force under section 360k(a), while Medtronic argues that PMA transforms the manufacturer's specifications into preemptive federal requirements. And although Medtronic cites various Federal Register notices and congressional reports, Petitioners believe that each supports their view when read in context.

If the Court grants the petition, there will be time enough to respond to Medtronic's merits arguments in detail. For present purposes, the depth of the disagreement on the merits only underscores the need for review. The parties' submissions make clear that courts have come down on both sides of the question presented, creating conflicts as to both aspects of the two-pronged analysis outlined in *Lohr*. In addition, as discussed in the petition (at 23-24), some courts have effectively ignored that analysis, disregarding, in particular, the Court's majority opinion with respect to the state-law side of the inquiry, which rejects preemption of generally applicable state law, such as the common-law duties on which Petitioners rely here. The conflicting decisions on the question presented, like the parties' positions, are irreconcilable and can be resolved only by this Court.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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In the Supreme Court of the United States

M. R. KNISLEY, *et al.*,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts petitioners' state common law damages claims challenging the design, production, distribution, and labeling of Medtronic's Model 4004 and Model 4004M pacemaker leads, where those devices were granted pre-market approval (PMA) by the Food and Drug Administration (FDA) and where each of petitioners' claims would impose requirements relating to the safety or effectiveness of the devices that would be "different from" or "in addition to" the federal requirements embodied in the FDA's pre-market approval of those devices.

RULE 29.6 STATEMENT

Respondent Medtronic, Inc. is a publicly traded corporation and has no corporate parent. No other publicly held company owns 10 percent or more of respondent's stock.

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BRIEF FOR THE RESPONDENT IN OPPOSITION

On at least two occasions in the last four years, this Court has denied petitions for certiorari virtually identical to the petition presented here. See *Martin* v. *Medtronic, Inc.*, 534 U.S. 1078 (2002); *Kemp* v. *Medtronic, Inc.*, 534 U.S. 818 (2001). The grounds for denying certiorari in those cases, already ample at that time, are even stronger today.

Contrary to petitioners' assertion (Pet. 1), the lower courts are *not* "deeply divided" regarding the application of *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). Quite the opposite. A clear and growing consensus has emerged that—consistent with this Court's teaching in *Lohr*—FDA premarket approval (PMA) of a medical device preempts conflicting state law claims arising from the design, manufacture, distribution, and labeling of such a device. Every court of appeals to have considered the issue in the past five years has concluded, as did the Sixth Circuit below, that the FDA's vigorous PMA process establishes device-specific federal requirements that, pursuant to 21 U.S.C. § 360k(a), preempt state common law damages claims that would effectively create state requirements "different from" or "in addition to" the federal requirements.

While there is some vestigial inconsistency in the lower courts' interpretations of *Lohr*, the remaining conflict is increasingly stale and likely to disappear even without this Court's intervention. The only cases to hold that state common law damages claims are never preempted by PMA approval were decided nearly a decade ago, shortly after this Court's decision in *Lohr*. Since then, this Court's subsequent decisions in *Geier* v. *American Honda Motor Co., Inc.*, 529 U.S. 861 (2000), and *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), have given clear guidance on the proper interpretation of *Lohr*. Moreover, just last year, the United States filed an *amicus curiae* brief in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004), setting forth the FDA's considered opinion that, under the relevant FDA regu-

lation, approval of a medical device through the PMA process generally preempts state common law claims arising from the use of such a device. Given *Geier*, *Buckman*, and the recent *amicus* brief in *Horn*, the few lower courts that had initially misinterpreted *Lohr* are likely to revise their aberrant views without further action by this Court.

STATEMENT

The petition provides almost no information about either the claims that petitioners actually raised below or the lengthy and comprehensive PMA process to which the specific medical devices at issue were subjected. After briefly outlining the background legal structure applicable to preemption under the Medical Device Amendments (MDA), 21 U.S.C. §§ 360c *et seq.*, to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, we set forth these critical facts.

A. The Regulatory Structure Of The Medical Device Amendments.

In 1976, Congress enacted the MDA, which vastly expanded the authority of the FDA to regulate medical devices. At the same time that it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. REP. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including in the MDA a "general prohibition on non-Federal regulation." *Id.* at 45. That general prohibition, which also serves to safeguard the uniformity of the federal regulatory scheme, broadly provides that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable * * * to the device" under federal law. 21 U.S.C. § 360k(a).

This Court has twice considered the preemptive scope of the MDA—in *Lohr* and, more recently, in *Buckman*. In a

fractured opinion, the *Lohr* Court held that the MDA's express preemption clause did not bar state law tort actions challenging the design, manufacture, or labeling of "Class III" devices (*i.e.*, those that either (1) are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or (2) "present[] a potential unreasonable risk of illness or injury," *id.* § 360c(a)(1)(C)), if those devices had been approved for sale through a simple "premarket notification" under the "510(k)" process as the "substantial[] equivalent" of a device in existence before the passage of the MDA. See *Lohr*, 518 U.S. at 492-494.

Explicitly differentiating the 510(k) notification process, at issue in *Lohr*, from the PMA process at issue here, the *Lohr* Court noted that "[t]he § 510(k) notification process is by no means comparable to the PMA process." *Id.* at 478–479. Thus, "[b]efore a new Class III device may be introduced to the market" via the far more exacting PMA process,

> the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance" [in the PMA process] is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.

518 U.S. at 477 (citations omitted). The Court contrasted this "rigorous" review with the 20 hours typical for a 510(k) review. *Id.* at 479. Because the device at issue in *Lohr* had been marketed "without running the gauntlet of the PMA process," *id.* at 494, the *Lohr* Court never addressed the preemptive scope of the PMA process.